UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF OHIO
EASTERN DIVISION

KAID C. MUSGRAVE, et al.,

Plaintiffs,

v.

Case No. 2:09-cv-01029
JUDGE GREGORY L. FROST
Magistrate Judge Mark R. Abel

BREG, INC. AND LMA, NORTH AMERICA, Inc., et al.,

Defendants.

OPINION AND ORDER

This matter is before the Court on Defendant[1] Breg, Inc.'s ("Breg or Defendant") Motion for Summary Judgment (ECF No. 103), Plaintiffs' Memorandum in Opposition to Defendant's Motion for Summary Judgment (ECF No. 119), the Reply Memorandum in Support of Breg's Motion for Summary Judgment (ECF No. 133), Plaintiffs' Motion for Partial Summary Judgment (ECF No. 109), Breg's Response in Opposition to Plaintiffs' Motion for Summary Judgment (ECF No. 118), and Plaintiffs' Reply in Support of Plaintiffs' Motion for Partial Summary Judgment (ECF No. 134). For the reasons that follow, the Court **GRANTS in part and DENIES in part** Defendant's motion and **DENIES** Plaintiffs' motion.

I. Background

Plaintiff Kaid C. Musgrave was seventeen years old in 2003 when he injured his right shoulder during a football game. On November 4, 2003, Dr. Brad E. Brautigan performed arthroscopic surgery on Musgrave's shoulder at the Zanesville Surgery Center in Zanesville,

[1]On August 31, 2010, the parties stipulated to the dismissal of LMA North America, Inc., leaving Breg, Inc. as the only defendant in this action. (ECF No. 94.)

Ohio. After the surgery, Dr. Brautigan prescribed and implanted the catheter of a Breg infusion pain pump to administer local anesthetic for post-operative pain control. Dr. Brautigan used a Breg PainCare 3200 and placed the catheter intra-articularly, *i.e.*, inside the shoulder joint. Dr. Brautigan prescribed 0.5% Marcaine (an anesthetic known generically as bupivacaine) for use in the pump. The pain pump was removed two days later, on November 6, 2003.

Musgrave continued to experience problems with his right shoulder, and on December 17, 2004, underwent a second arthroscopic surgery. During this surgery, Dr. Brautigan observed osteoarthritic changes to the glenohumeral joint. Less than two years after using the Breg pain pump, Musgrave developed chondrolysis, which is the rapid loss of joint cartilage following some chemical, mechanical, infectious, immunological, or thermal insult. *See* Daniel J. Soloman, et al., Glenohumeral Chondrolysis After Arthroscopy: A Systematic Review of Potential Contributors and Causal Pathways, Arthroscopy 25:11:1329 (2009). The result of this cartilage loss is a joint that no longer has a smooth gliding surface to cover the ends of the bone, so the joint rubs bone against bone causing pain and stiffness. Due to this condition, Musgrave underwent a total right shoulder arthroplasty. He has a complete loss of cartilage in his shoulder and degenerative bone loss.

Musgrave and his parents (together "Plaintiffs") filed this action on November 13, 2009. Plaintiffs claim that the post-operative continuous injection of anesthetics directly into Musgrave's shoulder joint caused chondrolysis, leaving him with serious and permanent cartilage damage.[2] Plaintiffs' complaint contains claims for relief against Defendant for strict

[2]As of May 2010, there were more than 170 pain pump cases in litigation around the country. *See In re Ambulatory Pain Pump-Chondrolysis Prods. Liab. Litig.*, 709 F. Supp. 2d 1375, 1375, fn.1 (J.P.M.L. 2010). The Judicial Panel on Multi-District Litigation denied a

products liability, fraud, and punitive damages.

II. Standard

Summary judgment is appropriate "if the movant shows that there is no genuine issue as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). The Court may therefore grant a motion for summary judgment if the nonmoving party who has the burden of proof at trial fails to make a showing sufficient to establish the existence of an element that is essential to that party's case. *See Muncie Power Prods., Inc. v. United Techs. Auto., Inc.*, 328 F.3d 870, 873 (6th Cir. 2003) (citing *Celotex Corp. v. Catrett*, 477 U.S. 317, 322 (1986)).

The "party seeking summary judgment always bears the initial responsibility of informing the district court of the basis for its motion, and identifying those portions" of the record which demonstrate "the absence of a genuine issue of material fact." *Celotex Corp.*, 477 U.S. at 323. The burden then shifts to the nonmoving party who "must set forth specific facts showing that there is a genuine issue for trial." *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 250 (1986) (quoting Fed. R. Civ. P. 56(e)). "The evidence of the nonmovant is to be believed, and all justifiable inferences are to be drawn in his favor." *Id.* at 255 (citing *Adickes v. S. H. Kress & Co.*, 398 U.S. 144, 158-59 (1970)). A genuine issue of material fact exists "if the evidence is such that a reasonable jury could return a verdict for the nonmoving party." *Muncie Power Prods., Inc.*, 328 F.3d at 873 (quoting *Anderson*, 477 U.S. at 248). *See also Matsushita Elec. Indus. Co., Ltd. v. Zenith Radio Corp.*, 475 U.S. 574, 586 (1986) (the requirement that a dispute be "genuine" means that there must be more than "some metaphysical doubt as to the

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motion for centralization of these pain pump cases that was filed by several of the plaintiffs. *Id.*

material facts"). Consequently, the central issue is " 'whether the evidence presents a sufficient disagreement to require submission to a jury or whether it is so one-sided that one party must prevail as a matter of law.' " *Hamad v. Woodcrest Condo. Ass'n*, 328 F.3d 224, 234-35 (6th Cir. 2003) (quoting *Anderson*, 477 U.S. at 251-52).

III. Discussion

Plaintiffs filed product liability claims, a common law fraud claim, and a punitive damages claim. Defendant moves for summary judgment on all Plaintiffs' claims and also argues that, if Plaintiffs' claims survive summary judgment, Plaintiffs' recovery of non-economic damages should be capped. Plaintiffs move for partial summary judgment on their statutory product liability claims.

A. Products Liability

Plaintiffs' product liability claims are governed by the Ohio Product Liability Act ("OPLA"), Ohio Revised Code §§ 2307.71-.80. Plaintiffs' claims are based on Defendant's alleged inadequate warning regarding intra-articular injection of anesthetics and/or use of the pain pump after orthopedic surgery, the Breg PainCare 3200 pain pump's alleged defective design, and Breg's alleged breaches of express and implied warranties.

1. Inadequate Warning and Defective Design

Under the OPLA, a "product is defective due to inadequate warning or instruction" if:

> (1) It is defective due to inadequate warning or instruction at the time of marketing if, when it left the control of its manufacturer, both of the following applied:
>
> > (a) The manufacturer knew or, in the exercise of reasonable care, should have known about a risk that is associated with the product and that allegedly caused harm for which the claimant seeks to recover compensatory damages;

> (b) The manufacturer failed to provide the warning or instruction that a manufacturer exercising reasonable care would have provided concerning that risk, in light of the likelihood that the product would cause harm of the type for which the claimant seeks to recover compensatory damages and in light of the likely seriousness of that harm.

(2) It is defective due to inadequate post-marketing warning or instruction if, at a relevant time after it left the control of its manufacturer, both of the following applied:

> (a) The manufacturer knew or, in the exercise of reasonable care, should have known about a risk that is associated with the product and that allegedly caused harm for which the claimant seeks to recover compensatory damages;
>
> (b) The manufacturer failed to provide the post-marketing warning or instruction that a manufacturer exercising reasonable care would have provided concerning that risk, in light of the likelihood that the product would cause harm of the type for which the claimant seeks to recover compensatory damages and in light of the likely seriousness of that harm.

Ohio Rev. Code § 2307.76(A).

Under the OPLA a "product is defective in design or formulation" if:

(A) . . . at the time it left the control of its manufacturer, the foreseeable risks associated with its design or formulation as determined pursuant to division (B) of this section exceeded the benefits associated with that design or formulation as determined pursuant to division (C) of this section.

(B) The foreseeable risks associated with the design or formulation of a product shall be determined by considering factors including, but not limited to, the following:

> (1) The nature and magnitude of the risks of harm associated with that design or formulation in light of the intended and reasonably foreseeable uses, modifications, or alterations of the product;
>
> (2) The likely awareness of product users, whether based on warnings, general knowledge, or otherwise, of those risks of harm;

> (3) The likelihood that that design or formulation would cause harm in light of the intended and reasonably foreseeable uses, modifications, or alterations of the product;
>
> (4) The extent to which that design or formulation conformed to any applicable public or private product standard that was in effect when the product left the control of its manufacturer.
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> (5) The extent to which that design or formulation is more dangerous than a resonably [sic] prudent consumer would expect when used in an intended or reasonably foreseeable manner.
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> (C) The benefits associated with the design or formulation of a product shall be determined by considering factors including, but not limited to, the following:
>
> (1) The intended or actual utility of the product, including any performance or safety advantages associated with that design or formulation;
>
> (2) The technical and economic feasibility, when the product left the control of its manufacturer, of using an alternative design or formulation;
>
> (3) The nature and magnitude of any foreseeable risks associated with an alternative design or formulation.

Ohio Rev. Code § 2307.75(A), (B), (C).

As Defendant correctly points out, whether based on design, manufacture, or warning, Plaintiffs must show that Defendant knew or, in the exercise of reasonable care, should have known that continuous intra-articular infusion of anesthetics after orthopedic surgery could cause chondrolysis. Defendant argues that there is no issue of material fact as to this inquiry and it is, therefore, entitled to summary judgment on Plaintiffs' inadequate warning and defective design claims. Plaintiffs too argue that there is no issue of material fact as to whether Defendant knew or reasonably should have known that continuous intra-articular administration of anesthetic after orthopedic surgery could cause chondrolysis, and they are, therefore, entitled to summary

judgment on their inadequate warning and defective design claims. Neither Defendant's nor Plaintiffs' arguments are well taken.

To support their claims, Plaintiffs provide literature published from 1985 forward showing risks relating to the articular use of drugs. Plaintiffs also submit evidence that several surgeons presented cases of chondrolysis after pain pump use at an American Shoulder and Elbow Society meeting, including Defendant's causation expert. Plaintiffs submit an Adverse Event Report that Defendant received in 2002 related to reports of injuries involving cell death alleged to be associated with intra-articular orthopedic uses of Breg's pain pumps. Plaintiffs' experts opine that had Defendant exercised reasonable care, it would have known prior to Musgrave's November 2003 surgery that continuous intra-articular administration of anesthetic following orthopedic surgery could cause chondrolysis

Plaintiffs also point out that Defendant was required to obtain approval from the United States Food and Drug Administration ("FDA") for marketing their pain pumps through submission and approval of a 510k application. Defendant's line of pain pumps is referred to as the PainCare series, and it includes the PainCare 2000, 2000L, 3000, 3200, 4200 and e-PainCare. Defendant applied to the FDA for approval to market these pain pumps for use in orthopedic surgery or intra-articularly and the FDA denied the request. The FDA's rejection of Breg's applications for the pumps to be used in orthopedic surgery or in the joint space occurred multiple times, beginning in 1998, as can be seen by this memorandum from the FDA file regarding Defendant's 510k application:

> The 510k was originally submitted with an expanded indications for use, i.e., for continuous infusion of local anesthetic directly into the intra-articular site for post-operative pain management, however, there was no accompanying data to demonstrate that this device may be used safely and effectively with this use. I had

> conferred with Marie Schroeder, Sahar Dawisha MD, and Bernard Berne MD, of REDB; Mark Melkershon of ORDB, Michael Bazaral MD of DCRND; and Hung Trinh and Particia Cricenti of GHDB regarding the specific use for this device. It was generally agreed that additional information was required to determine the safety and effectiveness of the device with this use.
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> The indications for use was [sic] modified on 11/04/98 by the deletion of the intra-articular use and being replaced with "for general and orthopedic surgeries." On 11/09/98, a fax was forwarded by the sponsor with another indications for use revision. The indications for use is [sic] now limited to general surgery. *All references to orthopedic surgery and intra-articular use have been deleted* form [sic] the 510k. I suggested to the sponsor that if they conduct a study related to the safety and effectiveness of this device for intra-articular use, they should identify a medication that can be used in a slow, continuous infusion for pain management in the intra-articular site.

(ECF No. 105-2 at 4) (emphasis added).

Another example is the 510k application submitted on July 7, 2000, in which Defendant again included a statement that the pain pump was for use following orthopedic surgery. In response, FDA reviewer Irene Naveau sent a letter to Breg on August 14, 2000, in which she stated:

> As with the PainCare 2000, pumps of this nature are cleared for general surgical use. Your comparison to the Painbuster and SurgiPeace includes the indications for use with orthopedic procedures which is not included in your Indications for Use. Correctly, since this indication is not in your Indications for Use statement, it should not be used in other sections of your submission. It is recommended that any reference to orthopedic procedures be deleted.

(ECF No. 117-7 at 1.) Plaintiffs provide evidence that, regardless of this FDA history, Defendant marketed their pain pumps for the "off label" use of intra-articular infusion following orthopedic surgery.

As to Defendant's evidence, it submits the opinions of experts who opine that Defendant could not have known prior to Musgrave's November 2003 surgery that continuous intra-articular administration of anesthetic after orthopedic surgery could cause chondrolysis.

Defendant points to articles showing that orthopedic surgeons had been injecting local anesthesia intra-articularly following joint surgery for many years prior to Musgrave's surgery without reports of adverse effects. Defendant provides literature from the 1990s that analyzes the positive results of the intra-articular administration of bupivacaine after arthroscopic surgery. As to Plaintiffs' evidence regarding the FDA's failure to approve the intra-articular administration of analgesics after orthopedic surgery and Defendant's alleged "off label" marketing, Defendant argues, first, that this type of evidence is irrelevant to the inquiry before the Court, and second:

> Any claim that the FDA explicitly disallowed the orthopedic or intra-articular use of Breg's pumps, and any revisionist testimony from Ms. Navaeu or anyone else attempting to alter the regulatory history, cannot dispute these undisputed facts or preclude summary judgment. *See Scott v. Harris*, 550 U.S. 372, 380 (2007) ("When opposing parties tell two different stories, one of which is blatantly contradicted by the record, so that no reasonable jury could believe it, a court should not adopt that version of the facts. when deciding whether to grant summary judgment.").

(ECF No. 133 at 13.)

Defendant also argues that Plaintiffs' own expert's testimony undercuts their contention that Defendant knew or should have known of the risk of chondrolysis from intra-articular infusion of bupivacaine prior to Musgrave's surgery. Defendant quotes Plaintiffs' expert as stating that "the link between pain pumps and chondrolysis had not been established" in 2004. (ECF No. 133 at 9) (citing ECF No. 117-1 at 8).

Initially, the Court notes that throughout Defendant's briefs it inappropriately conflates testimony about causation with the issue of foreseeability of risks. That is, the issue before the Court is not whether the evidence establishes that pain pumps cause chondrolysis; but instead, whether Defendant knew or, in the exercise of reasonable care, should have known that the use of pain pumps for continuous intra-articular infusion of anesthetic following orthopedic surgery

could cause chondrolysis. These two inquiries are separate and distinct.

Also, the Court rejects Defendant's challenge to Naveau's testimony as revisionist and blatantly contradicted by the record. Naveau's testimony is supported by the documents taken from the FDA's business records.

Further, the Court also rejects Defendant's contention that Naveau's testimony and the FDA documents are irrelevant to the inquiry at hand. Defendant relies upon *Krumpelbeck v. Breg, Inc.*, 759 F. Supp.2d 958 (S.D. Ohio 2010) for this proposition. In that case, however, the court relied upon case law holding that no private right of action exists for a manufacturer's failure to seek and obtain FDA approval of a product. *See id.* at 970-72 (citing, *inter alia*, *Loreto v. Proctor & Gamble Co.*, 737 F. Supp. 2d 909, 2010 U.S. Dist. LEXIS 91699 (S.D. Ohio Sept. 3, 2010) ("Plaintiffs seek damages as a result of P&G's alleged failure to seek and obtain FDA approval before selling the Products in interstate commerce. No private right of action exists for such a claim, and insofar as Plaintiffs seek recovery for such alleged violations, those claims are dismissed."). In the instant action, Plaintiffs are not attempting to file a claim against Defendant for failure to obtain FDA approval for the use of the pain pumps intra-articularly following orthopedic surgery. Instead, Plaintiffs offer evidence of Defendant's failure to obtain FDA approval as support for their proposition that Defendant knew or, in the exercise of reasonable care, should have known that continuous intra-articular infusion of anesthetic after orthopedic surgery was unsafe.

That being said, the Court is informed by three opinions from this District regarding Defendant's pain pumps, including *Krumpelbeck*. In each of these cases, the plaintiffs suffered from chondrolysis that they claim was a result of a pain pump infusing continuous intra-articular

bupivacaine following orthopedic surgery. In *Hamilton v. Breg, Inc.*, No. 2:09-cv-146, 2011 U.S. Dist. LEXIS 77085 (January 20, 2011), the Honorable James L. Graham assessed the evidence before him, which is nearly identical to the evidence before this Court, as follows:

> The medical evidence that pain pumps could cause chondrolysis was at best fragmentary at the time of plaintiffs' surgeries. But there was a body of medical research extending over decades prior to the mid-2000's showing that chondrocytes (cells of cartilage tissue) could be harmed or killed when foreign substances were injected into a joint and that these cells were sensitive to irritants in a way that might give rise to concerns about any procedure that exposed them to irritants for an extended period of time. Perhaps this should have given manufacturers of pain pumps cause to be concerned about potential harm to cartilage by using a pump to continuously infuse a local anesthetic into a joint for hours or days at a time and to warn of such potential harm.
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> If plaintiffs' case on failure to warn was based solely on actual notice of the potential harm it would be a very close case. The main thrust of plaintiffs' failure to warn claim, however, is not on what Breg actually knew at the time of plaintiffs' surgeries but on what Breg should have known. Plaintiffs claim that a reasonably prudent medical device manufacturer in the position of Breg would have conducted tests to determine what effect the continuous infusion of local anesthetic into a joint would have on cartilage before marketing its product for such a use. Plaintiffs claim that reasonably simple and inexpensive testing would have revealed that such use of a pain pump was likely to cause chondrolysis. Plaintiffs support these arguments with [expert testimony].

Id. at *9-10. Judge Graham concluded that:

> If the jury accepts the testimony of plaintiffs' experts, plaintiffs could prevail on their claim that defendant's product was defective due to inadequate warning.
> . . . .
>
> Insofar as Ohio Rev. Code 2307.75 imposes liability for defective design based on a risk benefit analysis in which the risk is defined as "foreseeable" and a balancing which includes "the nature and magnitude of the risks of harm" and "the likelihood that the design or formulation would cause harm" and the extent to which the design is "more dangerous than a reasonably prudent consumer would expect" it seems clear that the plaintiffs' evidence described above could also lead a reasonable jury to find that defendant's product was defective in design.

Id. at 14-15.

Similarly, in *Schott v. I-Flow Corp.*, 696 F. Supp. 2d 898 (S.D. Ohio 2010), the Honorable S. Arthur Spiegel denied the defendant's motion for summary judgment:

> Defendant's summary judgment motion is premised on the theory that Plaintiffs have not adduced reliable expert opinions supporting general causation. Because the Court's instant ruling arrives at the opposite conclusion, Defendant's motion for summary judgment is denied. To the extent that Defendant's motion attacks Plaintiffs' specific causation, the Court finds Plaintiffs have proffered adequate evidence showing that Plaintiffs' experts have ruled out alternative causes as to each Plaintiff such that reasonable juries could find specific causation by a preponderance of the evidence.

Id. at 905-06.

Defendant argues that this Court should disregard these two opinions in favor of *Krumpelbeck v. Breg, Inc.*, *supra*, in which the Honorable Timothy S. Black granted Breg's motion for summary judgment. Defendant's request is not well taken.

Unlike *Hamilton* and *Schott*, *Krumpelbeck* is readily distinguishable from the instant action. That is, after Judge Black granted summary judgment to Breg in *Krumpelbeck*, the plaintiff filed a motion to alter or amend the judgment under Rule 60(b) of the Federal Rules of Civil Procedure, suggesting that the court "overlooked" the testimony of one of the plaintiff's experts. Judge Black, in his opinion and order denying the plaintiff's motion to alter or amend the judgment explained:

> On December 2, 2010, after the pleadings were fully ripe for review, Plaintiff filed Dr. Parisian's expert report as a supplementary exhibit to the summary judgment record. (Doc. 69). <u>However, Plaintiff failed to include any explanation whatsoever as to how the 82 page report supported her memorandum in opposition</u>.
>
> On December 23, 2010, seven weeks after filing her memorandum, and only four days before the Court issued its Order, Plaintiff filed Dr. Parisian's deposition testimony - among twelve other deposition transcripts - as a stand-alone document with no explanation of their relation to any existing pleading. (Doc. 77, see also Docs. 72-84). On December 27, 2010, the Clerk entered the Court's order granting summary judgment in favor of the Defendant on all claims. (Doc. 86).

> The Plaintiff states that the Court perhaps "overlooked" Dr. Parisian's deposition in ruling on the motion. (Doc. 87 at 1). Actually, however, the Court finalized its Order granting summary judgment on December 23, 2010, before Plaintiff filed 2,827 pages of deposition transcripts. The Court sent the Order for docketing on Thursday, December 23, 2010, but because Friday was Christmas Eve, the Order was not docketed until the following Monday, December 27, 2010.
>
> S. D. Ohio Civ. R. 7.2(d) states that "all evidence then available shall be discussed in, and submitted no later than, the primary memorandum of the party relying upon such evidence." Here, it is undisputed that neither the Dr. Parisian deposition nor the report are "new evidence," but have existed since May 15, 2009 and April 17, 2009, respectively. We have Rules of Civil Procedure for good reason. Allowing Plaintiff to withhold the evidence and then file it long after the opposition has submitted their final brief in the matter, deprives them of an of an opportunity to reasonably examine the evidence and discuss it in the briefing. Moreover, the rules are in place so that a court may begin reviewing, analyzing, and drafting an order after the issues are ripe for review. If a party is permitted to "supplement" the recorded with thousands of documents that were clearly anticipated and not newly discovered - then this court would routinely waste valuable time and resources relying on an incomplete record in drafting an order. Int his instance especially, it is clear that counsel knew it was going to supplement the record and yet failed to mention this fact to the Court.

Krumpelbeck v. Breg, Inc., 1:09-cv-91, slip op. (June 21, 2011) (emphases in original).

Plaintiffs here had no such difficulty submitting their expert testimony to this Court. Therefore, the Court finds the instant action is more analogous to *Hamilton* and *Schott*, wherein the plaintiffs timely provided their evidence to the respective courts.

Based on the foregoing, the Court concludes that, like the *Hamilton* and *Schott* courts' conclusions, if the jury accepts the testimony of Plaintiffs' experts, Plaintiffs could prevail on their inadequate warning and defective design claims. Similarly, however, if the jury accepts the testimony of Defendant's experts, Defendant could prevail on Plaintiffs' inadequate warning and defective design claims. Therefore, Defendant's liability under the OPLA on these two claims present genuine issues of material fact that prohibit summary judgment in either Plaintiffs' or Defendant's favor. Accordingly, the Court **DENIES** Defendant's Motion for Summary

Judgment on Plaintiffs' inadequate warning and defective design claims and **DENIES** Plaintiffs' Motion for Partial Summary Judgment.

2. Breach of Express or Implied Warranty and Nonconformance

Plaintiffs argue that Defendant breached express and implied warranties by making oral and written representations concerning their pain pump's safety, quality, and character that did not conform to reality. Plaintiffs further argue that the pain pumps were not cleared by the FDA to be used intra-articularly following orthopedic procedures nor were they known to be safe and effective for such procedures. Defendant contends that these warranty claims fail because they were abrogated by the OPLA. Defendant is correct as to common law breach of express and/or implied warranty claims. *See* Ohio Rev. Code § 2307.71(B) ("Sections 2307.71 to 2307.80 of the Revised Code are intended to abrogate all common law product liability claims or causes of action"); *Miller v. Alza Corp.*, 759 F. Supp. 2d 929, 943 (S.D. Ohio 2010) ("common law warranty claims have also been abrogated by the OPLA, and therefore, insofar as Plaintiff asserts warranty claims under the common law, those claims have been abrogated by virtue of O.R.C. § 2307.71(B)"). Thus, the Court **GRANTS** Defendant's Motion for Summary Judgment on Plaintiffs' common law breach of implied and/or express warranty claims.

As to Plaintiffs' claim involving a statutory breach of warranty, that claim is more properly referred to as a failure to conform to representations claim. *See Alza Corp.*, 759 F. Supp. 2d 942-44 (separating OPLA failure to conform to representations claims from statutory breach of warranty claims).[3] To prevail on a failure to conform to representations claim, a

[3]The *Alza Corp.* court noted that, in products liability litigation, "Courts in this District have also determined that statutory breach of warranty claims filed pursuant to Ohio's codification of the Uniform Commercial Code ("UCC") in O.R.C. Chapter 1302 are not

plaintiff must prove that:

> (1) Defendant "made a representation as to a material fact concerning the character or quality of the" [pain pump]; (2) that the [pain pump] failed to conform to Defendants' representation; (3) justifiable reliance on Defendants' representation; and (4) that such reliance directly and proximately caused the alleged injuries.

Id. at 942 (citing *Westfield Ins. Co. v. HULS Am., Inc.*, 128 Ohio App.3d 270, 295, 714 N.E.2d 934 (Ohio App. 1998) (citing *Gawloski v. Miller Brewing Co.*, 96 Ohio App.3d 160, 165, 644 N.E.2d 731 (Ohio App. 1994)); *Barrett v. Waco Internatl, Inc.*, 123 Ohio App.3d 1, 702 N.E.2d 1216 (Ohio App. 1997); *White v. DePuy, Inc.*, 129 Ohio App.3d 472, 718 N.E.2d 450 (Ohio App. 1998)).

Defendant argues that "[t]here is no evidence that a Breg representative ever made a representation to Dr. Brautigan or Plaintiffs regarding the pump's safety for use in the joint space." (ECF No. 103-1 at 17.) This Court disagrees. Dr. Brautigan testified that a Breg sales representative "detailed" him on the use of a pain pump following an orthopedic surgery and indicated to the doctor that other surgeons were placing the catheter in the joint space. (Brautigan Dep. at 17-18, 21-22.) Accepting this evidence in the light most favorable to Plaintiffs and making all justifiable inferences in their favor, the Court concludes that this evidence raises a genuine issue of material fact as to whether a Breg representative made a representation to Dr. Brautigan regarding the pain pump's ability to be used safely intra-

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abrogated by the OPLA. 759 F. Supp.2d 929, 943 (citing *CCB Ohio LLC v. Chemque, Inc.*, 649 F. Supp. 2d 757 (S.D. Ohio 2009) (stating that "Plaintiffs' warranty claims can find a basis grounded in the Uniform Commercial Code and therefore are not claims abrogated by the OPLA"); *Donley v. Pinnacle Foods Group, LLC*, No. 2:09-cv-540, 2009 U.S. Dist. LEXIS 120503, 2009 WL 5217319, at *4 (S.D. Ohio Dec. 28, 2009) (same). In this action, however, Plaintiffs do not allege a breach of warranty claim pursuant to Ohio's codification of the UCC and instead claim that there statutory claim is grounded in the OPLA.

articularly following orthopedic surgery.

Consequently, the Court **DENIES** Defendant's Motion for Summary Judgment as it relates to Plaintiffs' failure to conform to representations claim.

B. Fraud

Plaintiffs have filed a common law fraud claim against Defendant. Defendant argues that it is entitled to summary judgment on Plaintiffs' fraud claim because that claim is abrogated by the OPLA and that even if it were not, it still fails as a matter of law. This Court disagrees.

> [In Ohio] [t]he elements of an action in actual fraud are: (a) a representation or, where there is a duty to disclose, concealment of a fact, (b) which is material to the transaction at hand, (c) made falsely, with knowledge of its falsity, or with such utter disregard and recklessness as to whether it is true or false that knowledge may be inferred, (d) with the intent of misleading another into relying upon it, (e) justifiable reliance upon the representation or concealment, and (f) a resulting injury proximately caused by the reliance.

Gaines v. Preterm-Cleveland, Inc., 33 Ohio St. 3d 54, 55 (Ohio 1987) (citations omitted).

Contrary to Defendant's contention, actions for fraud are outside the scope of the OPLA's abrogation. *CCCB Ohio LLC v. Chemque, Inc.*, 649 F. Supp. 2d 757, 763 (S.D. Ohio 2009) ("the Court finds actions for fraud and negligent misrepresentation as outside the scope of the OPLA's abrogation").

As to the merits of Plaintiffs' fraud claim, Defendant argues: "Plaintiffs' fraud claims rest on the fundamentally flawed premise that Breg knew that continuous administration of anesthetic in the joint space could cause chondrolysis, but told consumers—with the intent to defraud, deceive, and mislead them—that the pumps were safe for use." (ECF No. 103-1 at 20.) Plaintiffs, however, contend that their claim does not rest solely on Defendant's misrepresentations about safety. Instead, Plaintiffs assert that their claim includes Defendant's

fraudulent concealment and omissions concerning the regulatory status and the uses to which the pain pumps could be utilized. Plaintiffs present evidence that the pain pump at issue here was not approved for intra-articular placement following orthopedic surgery. This Court must view that evidence in the light most favorable to Plaintiffs and draw all justifiable inferences in their favor. The credibility and weight to be given that evidence in this instance will be for the jury to determine. At this juncture, the evidence is sufficient to raise a genuine issue of material fact as to whether Defendant committed fraud in their marketing of the pain pump to orthopedic surgeons.

Accordingly, the Court **DENIES** Defendant's Motion for Summary Judgment as it relates to Plaintiffs' fraud claim.

C. Punitive Damages

To recover punitive damages in a strict products liability case, Plaintiffs must prove by "clear and convincing evidence" that the injury sustained "was the result of misconduct of the manufacturer or supplier in question that manifested a flagrant disregard of the safety of persons who might be harmed by the product in question." Ohio Rev. Code Ann. § 2307.80. Defendant argues that it is entitled to summary judgment on this claim because Plaintiffs have not presented evidence that Defendant acted with flagrant or conscious disregard for their safety. On the other hand, Plaintiffs argue that they have presented evidence that the FDA repeatedly rejected Defendant's request to promote its pain pumps for intra-articular and orthopedic uses and Defendant's failure to act on the literature, presentations, and adverse events warning or testing, evince a flagrant disregard of the safety of persons who might be harmed by the pain pumps.

Under current Ohio law, liability for punitive damages in a tort action is to be determined

by the trier of fact (generally a jury), and if the factfinder determines that punitive damages should be awarded, the amount of punitive damages is determined by the court. Ohio Rev. Code § 2307.80(B); *Hunter v. Columbus*, 139 Ohio App. 962, 746 N.E.2d 246, 251 (Ohio Ct. App. 2000) (the question of whether a person has acted recklessly "is almost always" a question for the jury).

The Court finds that the evidence before it is not so one-sided that Defendant must prevail as a matter of law, and instead, presents a sufficient disagreement to require submission to a jury. Thus, the Court **DENIES** Defendant's Motion for Summary Judgment as it relates to Plaintiffs' punitive damages claim.

D. Non-Economic Damages

Defendant argues that, if Plaintiffs' claims survive summary judgment, Plaintiffs' non-economic damages should be capped pursuant to the Ohio Revised Code § 2315.18(B)(2). That statutory provision limits non-economic damages in tort actions to the greater of $250,000 or three times the economic loss to a maximum of $350,000 per plaintiff or $500,000 for each occurrence that is the basis of the tort action. The statute provides for exceptions to the cap for certain types of injuries:

> There shall not be any limitation on the amount of compensatory damages that represents damages for noneconomic loss that is recoverable in a tort action to recover damages for injury or loss to person or property if the noneconomic losses of the plaintiff are for either of the following:
>
> (a) Permanent and substantial physical deformity, loss of use of a limb, or loss of a bodily organ system;
>
> (b) Permanent physical functional injury that permanently prevents the injured person from being able to independently care for self and perform life-sustaining activities.

Ohio Rev. Code § 2315.18(B)(3)(a), (b).

While neither party alerts the Court's attention to the effective date of this statute, the Court finds that date dispositive to the determination of whether this statute applies to this action. That is, Ohio Revised Code § 2315.18 became effective on April 7, 2005. That date is after Musgrave's surgery but before the date Plaintiffs filed the instant action. Thus, the provision does not apply to Plaintiffs here unless it is applied retroactively to the date of the injury or the relevant date for determining whether the statute applies is the date a plaintiff files a lawsuit based on the injury.

The Northern District of Ohio recently dealt with a case directly on point. In *Heffelfinger v. Connolly*, No. 3:06-CV-2823, 2009 U.S. Dist. LEXIS 6441 (N.D. Ohio Jan. 15, 2009), the court addressed a situation where the plaintiff's injury occurred before the effective date of Ohio Revised Code § 2315.18 and the plaintiff filed suit after the effective date of the statute. The court started its discussion with an analysis of whether the statute applied retroactively. This Court finds that analysis persuasive and adopts it herein:

> First, a "court must determine . . . whether the statute is expressly made retroactive." Mastellone [v. Lightening Rod Mutual Insurance Co.], 175 Ohio App. 3d [23,] 31, [2008 Ohio 311, 884 N.E.2d 1130 (2008)]. Under Ohio law, "statutes are presumed to apply prospectively unless expressly declared to be retroactive." O.R.C. § 1.48; *see also Van Fossen v. Babcock & Wilcox Co.*, 36 Ohio St. 3d 100, 105, 522 N.E.2d 489 (1988).
>
> Second, if the legislature expressly made the statute retroactive, a court must determine whether the statute is "substantive or remedial in nature." *Mastellone, supra*, 175 Ohio App. 3d at 31; *State v. La Salle*, 96 Ohio St. 3d, 178, 181, 2002 Ohio 4009, 772 N.E.2d 1172 (2002). If the statute retroactively alters the parties' substantive rights it may violate Section 28, Article II of the Ohio Constitution. Statutes affecting only remedies, however, may apply retroactively. *Groch* [*v. Gen. Motors Corp.*], *supra*, 117 Ohio St. 3d [192,] 224 [2008 Ohio 546, 883 N.E.2d 377 (2008)]; *see also* Ohio Const. Section 28, Article II ("The general assembly shall have no power to pass retroactive laws . . . .").

> Ohio courts have concluded that the General Assembly did not intend the instant statute to be retroactive. In *Mastellone*, *supra*, 175 Ohio App. 3d at 31, the court concluded that another provision of the statute at issue in this case is not retroactive because it "contains no express statement about being retroactive." The court considered O.R.C. § 2315.21(B), which provides for a bifurcated trial on request in tort actions involving punitive and compensatory damages. *Id.* O.R.C. § 2315.21(B), at issue in that case, was part of Ohio's tort reform bill, S.B. 80, which became effective on April 7, 2005. *Id.* The court found that the Ohio General Assembly "gave no indication of retroactivity," except in limited cases, such as asbestos claims. *Id.* at 31, n.2.
>
> As in *Mastellone*, the statutory provisions at issue, O.R.C. § 2315.21(D) and O.R.C. § 2315.18(B) were part of S.B. 80. Neither provision contains express language indicating a retroactive effect. Therefore, the provisions in this case have no retroactive effect.

Id. at 4-6.

The *Heffelfinger* court next considered whether the relevant date for determining whether the statute applies is the date of the injury or the date the plaintiff filed the action. Again, the Court finds the analysis persuasive and adopts it herein:

> Courts have held that the relevant date for determining whether the new O.R.C. § 2315.21 applies is the date the conduct giving rise to the plaintiff's cause of action occurred. In *Blair v. McDonagh*, 177 Ohio App. 3d 262, 282, 2008 Ohio 3698, 894 N.E.2d 377 (2008), the court considered a more complex scenario than the instant case -- some of the defendant's unlawful conduct occurred before the new cap's effective date of April 7, 2005, and some of defendant's conduct occurred after that date. The court held that the new cap does not apply to "causes of action that arose before the statute's effective date even if some of the conduct giving rise to the cause of action occurred after the effective date." *Id.*
>
> In the instant case, none of the defendant's conduct took place after the statute's effective date. Although in Blair the court considered only the punitive damages provision, the same logic applies to the non-economic damages provision. The damages cap, therefore, does not apply to the plaintiff's cause of action.
>
> Ohio courts construing earlier damage cap statutes have similarly concluded that the date plaintiff's cause of action accrued, not the date that plaintiff filed suit, is the relevant date for determining whether a new damages regime applies. *See Uebelacker v. Cincom Systems Inc.*, 80 Ohio App. 3d 97, 102, 608 N.E.2d 858 (1992) (damage cap statute does not apply where the "cause of action arose prior to

> the effective date" of the statute); *Akron-Canton Waste Oil v. Safety-Kleen Oil Services*, 81 Ohio App. 3d 591, 607, 611 N.E.2d 955 (1992) (Where plaintiffs filed suit after the effective date of a damage cap statute, it does not apply unless "(1) the claims warranting the punitive damages arose, or (2) the conduct alleged occurred" before the statute's effective date.).
>
> Defendant's request that I apply the new statute to plaintiff's claims arising from the November 29, 2004, accident therefore requires a retroactive application. Because the statute does not permit retroactive application, I cannot apply the cap to plaintiffs' claims.

Id. at 6-8.

Based on the foregoing analysis, the Court finds that Ohio Revised Code § 2315.18 does not apply to this action. Accordingly, the Court **DENIES** Defendant's Motion for Summary Judgment as it relates to its request for a statutory damages cap.

IV. Conclusion

For the reasons set forth above, the Court **DENIES** Plaintiffs' Motion for Partial Summary Judgment (ECF No. 109) and **GRANTS** Defendant's Motion for Summary Judgment as it relates to Plaintiffs' common law breach of implied and/or express warranty claims and **DENIES** the remainder of Defendant's motion (ECF No. 103).

IT IS SO ORDERED.

/s/ Gregory L. Frost
GREGORY L. FROST
UNITED STATES DISTRICT JUDGE